JC09 Rec'd PCT/PTO 21 FEB 2001

FORM PTO-1390
REV. 5-93

US DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEYS DOCKET NUMBER
P01,0064

U.S.APPLICATION NO. (if known, see 37 CFR 1.5)
09/763387

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/SE99/01383	17 August 1999	31 August 1998

TITLE OF INVENTION

DEVICE IN CONNECTION WITH PACERS

APPLICANT(S) FOR DO/EO/US

PAUL BRAND and ROLF HILL

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of International Application as filed (35 U.S.C. 371(c)(2)) - drawings attached.
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2) - drawings attached.

7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). Un-executed

10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; **(PTO 1449, Prior Art, Search Report).**

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.

13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☒ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☒ Other items or information:
    a. ☒ Submission of Formal Drawings
    B. ☒ Express Mail Label EL 655299988US

JC03 Rec'd PCT/PTO 21 FEB 2001

U.S.APPLICATION NO. (if known, see 37 C.F.R. 1.5) 09/763387	INTERNATIONAL APPLICATION NO. PCT/SE99/01383	ATTORNEY'S DOCKET NUMBER P01,0064

17. ☒ The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): Search Report has been prepared by the EPO or JPO $860.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482)$690.00		
No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2) $760.00		
Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO $1000.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).	$	

Claims	Number Filed		Number Extra	Rate		
Total Claims	11	- 20 =	0	X $18.00	$	
Independent Claims	1	- 3 =		X $ 80.00	$ 00	
Multiple Dependent Claims				$270.00 +		
TOTAL OF ABOVE CALCULATIONS =					$860.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)					$	
SUBTOTAL =					$860.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +					$	
TOTAL NATIONAL FEE =					$860.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property +					$	
TOTAL FEES ENCLOSED =					$860.00	
					Amount to be refunded	$
					charged	$

a. ☒ A check in the amount of $860.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 501519 . A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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Steven H. Noll
SIGNATURE

Steven H. Noll
NAME

28,982 (Registration No.)

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09/763387

CERTIFICATE OF MAILING BY EXPRESS MAIL

"Expresss Mail" Mailing label Number EL 655299988US

Date of Deposit: February 21, 2001

I hereby certify that this correspondence is being deposited with the United States Postal "Express Mail Post Office To Addressee" service under 37 CFR 1.10(c) on the date indicated above and is addressed to:

BOX PCT
Hon. Assistant Commissioner for Patents
Washington DC 20231

Case Number: P01,0064

International Application No. PCT/SE99/01383

International Filing Date: 17 AUGUST 1999

Title: DEVICE IN CONNECTION WITH PACERS

Applicant: Paul Brand et al

Enclosed are the following documents:

International Application as filed, drawings, attached;
PTO 1390 in duplicate;
Un-executed Declaration
Amendment A Prior to Action
Substitute Specification
Submission of Drawings
Government Filing Fee
Postcard

L. Gardner

Signature of Person mailing documents and fees

BOX PCT
IN THE UNITED STATES DESIGNATED OFFICE
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
UNDER THE PATENT COOPERATION TREATY-CHAPTER II

AMENDMENT "A" PRIOR TO ACTION AND SUBMISSION OF SUBSTITUTE SPECIFICATION

APPLICANTS: Brand et al.
ATTORNEY DOCKET NO. P01,0064
INTERNATIONAL APPLICATION NO: PCT/SE99/01383
INTERNATIONAL FILING DATE: August 17, 1999
INVENTION: "DEVICE IN CONNECTION WITH PACERS"

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT application as follows, and request entry of the Amendment prior to examination on the merits in the United States National Examination Phase.

IN THE TITLE:

Please cancel the present title and substitute the following title therefor:

--PACEMAKER HOUSING WITH LEAD CONNECTION ASSEMBLY--

IN THE SPECIFICATION:

Applicants herewith submit a substitute specification pursuant to 37 C.F.R. §1.25(b), plus a marked up copy showing all changes therein. No new matter is contained in the substitute specification.

IN THE CLAIMS:

On page 11, cancel "Claims" and substitute
--**WE CLAIM AS OUR INVENTION**:-- therefor.

Please cancel claims 1 - 8 and substitute the following claims therefor:

9. A pacemaker comprising:

a metallic housing having a first wall with a first opening therein and a second wall with a second opening therein;

a metallic tubular member having a first tube end disposed in and attached to said first opening and an opposite second tube end disposed in and attached to said second opening, said tubular member being substantially continuous between said first tube end and said second tube end; and

a plurality of interior components disposed within said tubular member adapted to make electrical contact with contact surfaces of a contact plug adapted for insertion into said tubular member.

10. A pacemaker as claimed in claim 9 wherein said first and second tube ends are respectively bonded to said metallic housing at said first and second openings.

11. A pacemaker as claimed in claim 9 wherein said first and second tube ends are respectively welded to said metallic housing at said first and second openings.

12. A pacemaker as claimed in claim 9 wherein said metallic tubular member has at least one lateral opening therein, and having a contact surface disposed in said opening for establishing electrical contact between the interior of said metallic tubular member and an exterior of said metallic tubular member, said contact surface being electrically connected to at least one of said interior components.

13. A pacemaker as claimed in claim 12 further comprising an insulating ceramic plug disposed in and closing said opening, said ceramic plug being mechanically attached in said opening and holding said contact surface in said opening.

14. A pacemaker as claimed in claim 13 wherein said ceramic plug is soldered in said opening.

15. A pacemaker as claimed in claim 13 wherein said ceramic plug is bonded in said opening.

16. A pacemaker as claimed in claim 13 wherein said contact surface is a metallic ring and wherein said ceramic plug has an exterior with a lateral opening therein in registry with said lateral opening in said metallic tubular member allowing access to said ring from said exterior of said metallic tubular member.

17. A pacemaker as claimed in claim 16 wherein said metal ring has a central portion which is free of ceramic of said ceramic plug, producing a peripheral groove at an interior of said ring allowing access to said ring from said interior of said metallic tubular member.

18. A pacemaker as claimed in claim 9 further comprising a locking arrangement disposed at said second tube end, and accessible from said second tube end, adapted for locking an end of an electrode lead in said metallic tubular member.

19. A pacemaker as claimed in claim 18 wherein said locking arrangement is at least partially removable from said metallic tubular member to allow access to said end of said electrode lead.

IN THE ABSTRACT:

Please add the Abstract attached hereto as separately numbered page 13.

REMARKS:

The present Amendment makes editorial changes in the specification and claims to conform to the requirements of United States patent practice, and adds an Abstract. Claims 1-8 have been cancelled in favor of the claims presented herein solely because the amount of bracketing and underlining which would have been necessary in the original claims to conform those claims to the requirements of 35 U.S.C. §112, second paragraph, would have been unduly burdensome and confusing. Accordingly, no change in any of the claim language has been made to distinguish any of the claims over the teachings of the prior art of record, and therefore no difference in the claim language between the original claims and the claims presented herein is intended by the Applicants to be a surrender of any of the subject matter encompassed within the scope of original claims.

Early consideration of the PCT application on the merits is therefore respectfully requested.

Submitted by,

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ABSTRACT

A pacemaker has a metallic housing with a connector arrangement adapted to receive a contact plug, with contact surfaces, at the proximal end of an electrode lead. The connector arrangement includes a metallic tubular member with opposite ends which are welded or bonded to respective openings in the metallic housing. The metallic tubular member is substantially continuous along its length between the opposite ends. All components which are needed for making electrical contact with the contact surfaces of the lead are contained within the interior of the metallic tubular member.

SPECIFICATION

TITLE

"PACEMAKER HOUSING WITH LEAD CONNECTION ASSEMBLY"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to pacer housings and more particularly to those parts of the housing intended for connection to the electrode leads.

Description of the Prior Art

Implantable pacers normally have a pacer housing (also called can) containing electronic circuitry and a unit for electric power as well as different electrodes which are connected to the interior parts in the pacer housing and which are to be implanted in or in the vicinity of the heart. The electrodes are connected to the pacer by means of leads. The internal parts of the pacers have to be well protected against the internal environment, especially the body fluids in the body for a long period of time, which places strict requirements on all entries into the interior of the can and especially on the connections of the leads to the housing. At the same time it should be possible to disconnect the pacer from the implanted leads for replacement or servicing of the pacer. The connective parts of the pacer and the leads have largely been standardized so as to encompass a relatively deep female socket having a number of contact surfaces whereas the leads are provided with a male part comprising one or several corresponding peripheral, generally circular contact surfaces.

At present the connective part of the pacer housing containing the female socket is made of a transparent material, normally of epoxy resin, which is molded onto the housing and onto contacts extending outwardly from the housing. The male part of the leads is normally locked by means of set screws, although other fastening means have been suggested. The positioning and alignment of the different contact surfaces and of the fastening means or metallic threads for the set screws prior to the molding of the connective part is, however, complicated and the delay in the manufacturing process incurred by the curing of the epoxy resin is considerable.

It would thus be desirable if the molding procedure could be dispensed with.

It has been discussed that these complexities could be avoided by designing the pacer with a socket located inside the metal housing. This kind of sockets, sometimes termed "black holes", are not used at present.

United States Patent No. 4,934,366 and United States Patent No. 5,324,311, both of which are incorporated by reference, describe two interior sockets or black holes for pacers. Both designs employ a tubular member formed by a number of longitudinally alternating sections respectively made of metal and insulating ceramics. An end section of metal can be welded or bonded to an opening in the pacer housing by means of a flange. The use of different materials,

however, sets high standards in regard to precision and durability of the components as well as in the assembly procedure thereof. This is especially important since the interior sockets must meet very high standards regarding the integrity of the interior of the pacer housing during long times of implantation in a demanding environment. The manufacture of these known sockets thus is relatively complicated.

SUMMARY OF THE INVENTION

An object of the invention is to avoid the aforementioned molding procedure and to simplify the design of an interior socket of a pacer connector while still meeting the required high standards for a pacer housing.

DESCRIPTION OF THE DRAWINGS

Fig 1 shows a conventional pacer housing with a transparent, molded connective part.

Fig 2 shows a known lead with a male connective part.

Figs 3 - 6 show a preferred embodiment of the connective part in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig 1 illustrates a conventional pacer housing 1 having a 15 molded, transparent connective part 2. The connective part 2 includes a female socket 3. The inner end of the socket 3 is provided with a longitudinal bore 7 having a relatively small diameter. The bore 7 is provided with a contact surface 4 adjacent to which threads 5 for a set or

lock screw are located in a bore 6 oriented orthogonally relative to the female socket. The housing is hermetically sealed also in relation to the molded part 2 and the contact between the interior electronics and the contact surface 4 is achieved by means of a feed-through. The feed-through is formed by a ceramic plug, typically made of alumina, into which one or more leads have been soldered. This lead is bonded (e.g. ultrasonically welded) to the electronics and to the contact surface 4. The ceramic plug is soldered or brazed by means of gold into a sleeve made of titanium. This operation may be made at any time before the assembly of the pacer housing. The sleeve is welded into an opening in the housing in a sealing manner during the assembly of the pacer housing that normally consists of two halves. Before the connective part is molded onto the housing, these halves are welded together and sealed.

Fig 2 illustrates a lead 15 comprising a proximal connecting plug 10 and a distal, transvenous, intracardial electrode 16 as well as an attachment arrangement 17 for suturing the proximal end of the lead in the body of the patient. The connecting plug 10 is designed to be received in the socket 3 and the end thereof is provided with a longitudinally projecting contact pin 11 as well as a cylindrical body 17 provided with sealing rings 12, 13, 14 intended to engage and seal against the corresponding inner cylindrical surface of the female socket 3. The shape of the

pin 11 corresponds to the shape of the bore 7. When the plug 10 is inserted into the socket 3 the pin 11 engages the contact surface 4 and the set-screw in the bore 6 can be tightened against the pin 11 in order to securely lock the plug 10 in the socket 3. The complexities involved in holding the bores, contact surfaces and threads in position and keeping them open and free from the molding material during the molding process are evident.

For simplicity, the above known device has been illustrated as unipolar. A bipolar embodiment naturally will be more complex to manufacture. The preferred embodiments of the invention described below will relate to bipolar embodiments.

Figs 3 - 5 show a preferred embodiment of the invention comprising a tubular member 20. For clarity, the reference signs not repeated throughout all drawings.

The tubular member 20 is a tube 21 with two open ends 22, 23. Each end is to be welded into a respective opening in the pacer housing. The tube 21 is made of the same metal as the pacer housing, in this case titanium. The mid-section of the tube 21 is provided with two relatively small lateral openings 24, 25. The openings 24, 25 are sealed by means of a ceramic plug 26 fitting snugly in the tube 21 and soldered with gold against the inside of the tube 21. Two contact rings 27, 28 - plug overlapping the lateral openings. The ceramic plug also originally could consist of several separate parts with the

contact rings held between and soldered to these parts, thus uniting the parts of the plug to a unitary unit. The soldered junctions then would form an efficient seal.

It should be noted that the size of the openings 24, 25 which are necessary to allow the bonding of the leads to the parts of the contact rings accessible through the openings 24, 25 and 31, 32 is small, in relation to the entire circumference and to the length of the tube 21. The openings thus do not affect the structural integrity of the tube 21. The contact rings 27, 28, moreover, overlap the openings and are bonded thereto by means of the intermediate layer of ceramics, in this way strengthening the area in which said openings are located.

Typical dimensions for a tube intended to house a standard IS-1 male connector are for instance an inner diameter of 20 mm, a wall thickness of 0.3 mm (i.e. the same as the thickness of typical pacer housing walls) and a diameter of the holes 24, 25 of about 2 mm. A minimum area of about 4 mm^2 is necessary for the equipment presently used for bonding leads to metallic surfaces. The length of the tube 21 is of course adapted to the specific housing into which it is to be placed, but might typically be about 25 mm.

These dimensions of course can be varied as long as the tube remains structurally intact, i.e. as long as the tube has a strength and rigidity that is sufficient to prevent loads, including thermal stresses, on the housing and/or the

connector to be transferred as tensile forces to the ceramic parts. Of course, low tensile forces not exceeding the tensile strength of the ceramic could be accepted. Since there are standards regarding the loads a pacer housing and connector should be able to withstand and regarding the dimensions only would involve standard stress calculations and dimensioning well within the scope of the man in the art. It should be noted that this also could take the degree of soldering between ceramic plug and tube into account, since this would determine the extent to which tube and ceramic would function as a composite without going outside the ordinary skill of the man skilled in the art.

The ceramic plug is provided with an interior bore 10 corresponding to the shape of the male connector in the same way as the molded prior art female connector described above and thus includes interior sealing surfaces 52, 53 for engagement with the sealing rings on the male connector.

A part 30, 31 of the inside of the contact rings is not covered with the ceramic material. In this way two inner circumferential grooves are obtained in the inner bore of the ceramic plug. The bottom of the grooves consists of the metal in the contact rings. Two openings 32, 33 are also provided in the outer surface of the ceramic plug that may be made to coincide with the lateral openings 24, 25 in the tube wall. These openings give access to the contact rings 27, 28 when the ceramic plug has been mounted correctly in the tube 21.

Thus, when the ceramic plug 26 has been soldered or bonded into place, the openings 24, 25 will be completely sealed by the plug 26 although allowing electrical connection to the interior of the tube 21 via the contact rings 27, 28. To this extent the tubular member 20 can be manufactured in advance as desired.

Both ends of the prefabricated tube 21 can be welded to the pacer housing and the housing parts can be welded together after the connection of interior leads from the interior electronics to the contact rings 27, 28, should this be desired.

The remaining parts, i.e. the structures for achieving the contact between the contact rings and the contact surfaces on the male connector part on the lead, and for locking or fixating the male connector part in the socket, can easily be inserted afterwards. This means, for instance, that these parts would not interfere with the standard helium-based procedures for testing the housing with connector for leaks or that these parts would not be affected by the leak testing procedure.

Fig 3 shows the main components of the tubular member 20, the tube 21 with openings 24, 25, the ceramic plug 26, a fixation part 40 and two circular spring contacts 57, 58. The spring contacts are similar to the spring contacts used in United States Patent No. 4,934,366.

The fixation part 40, shown in more detail in Fig 4, is designed in the same way as the lead locking device disclosed in United States Patent No. 4,784,141, incorporated herein by reference, and has a hollow cylindrical part 41 fitting into the end of the tube 21. The inner end of the cylindrical part 41 is provided with an interior flange 42 with an inner conical surface 43. The locking device further comprises a resilient locking ring 44 located adjacent the flange 42. One side of the ring has a conical surface 45 that is complementary to the conical surface 43. The other side of the ring also has a conical surface 46 that is complementary to a conical surface 47 on a plug 48 provided with exterior threads 49 fitting into interior threads 50 on the inside of the cylindrical part 41. The outside of the plug 48 is provided with an O-ring 51 that is located in a peripheral groove 52 and sealingly engages the inside of the cylindrical part 41. When the plug 48 is screwed into the cylindrical part 41, the resilient ring 44 will be forced inwardly into contact with the contact pin of the male connector part by means of the interaction of the different conical surfaces, thus locking the contact pin inside the tube 21.

The tube 21 preferably is of the same material as the pacer housing, which normally is made of titanium. The ceramic plug may for instance be made of alumina, Al_2O_3, and the contact rings may for instance be made of stainless steel or of titanium.

In the above embodiment the ceramic plug has been illustrated as extending from the end of the tube and past the openings in the side of the tube. It is, however, only necessary that the ceramic plug cover the openings. The remaining part can be designed as a separate part inserted and bonded to the tube after the assembly of the pacer housing in a similar way as the fixation part 40.

Fig 4 shows the tube 21 with all component parts mounted.

Fig 5 shows how the tube 21 has been mounted in a pacer housing 60 and welded to openings 61, 62 in the openings via flanges located on the outside of the tube ends. Fig 5 also shows a male connector plug 110 inserted in the tubular member. The plug has a contact pin 111, a contact surface 118 and four sealing rings 112, 113, 114, 117. The resilient ring 44 grips the pin 111 and the sealing rings 112 - 114, 117 are in engagement with the interior sealing surfaces 52, 53.

The connector can be achieved in a simple way compared with the known molded connector means.

As mentioned above, the ceramic part can be soldered into the tube 21 in advance by similar methods as used when obtaining the feed-through in the prior art. The tube 21 then is placed in the openings in one of the pacer housing halves and conductors 55, 56 are bonded (typically by means of the electronic board 54 and to the parts of the contact rings that are accessible via the openings in the tube. The housing halves then are assembled and the two halves and the ends of

the tube are welded together by means of a laser beam to form a sealed unit. This unit then is tested for leakage, for instance by means of standard helium-based procedures. It should be noted that no other kinds of work operations than those already used in the prior art are necessary.

The pacer then is finished by slipping the resilient spring contacts into the respective interior grooves in the ceramic plug and by inserting and bonding the lead locking mechanism into place in the corresponding open end of the tube.

The new connective part thus is very simple to manufacture and to mount in the pacer housing. The welding and sealing of the housing only includes the additional step of welding the ends of the tube to the edges of the openings in the housing, which is done in the same operation as the welding of the two housing halves. After the welding operation, no further operations are necessary, except for the simple insertion of contact rings and lead locking mechanism.

Since the tube after the welding operation in principle forms an integral, load-carrying part of the pacer housing, a high degree of tightness and integrity is obtained. The tube will ensure a high strength and a high durability of the connective part, whilst the ceramic plug will ensure a high degree of tightness in view of the large contact area between ceramic plug and tube that can used for soldering, i.e. sealing.

Although a pacer housing with one tubular member has been illustrated, the housing of course can contain several members. The housing also wholly or partly could be made of openings holding the tube 21 are of metal or of a material allowing a bond of sufficient strength to the metal tube 21. Furthermore, although the tube 21 has been illustrated as having a circular cross-section, other cross-sections are possible.

An important advantage with the connector according to the invention is that the connecting pin 111 on the end of the lead can be reached from the outside through the end of the tube containing the lead locking mechanism. This will facilitate the removal of the male connector from the female socket since the pin 11 can be pushed outwardly through said second end by means of a tool if the male connector proves to be difficult to pull out. In the above, preferred embodiment it is sufficient to unscrew the threaded plug 48, thus exposing the end of the contact pin 111. Furthermore, in this state a stylet could be introduced into the longitudinal channel, for instance for repositioning the electrode with the aid of the internal electronics in the pacer. The plug 48 could also contain a sealable, longitudinal bore, for instance sealed by a screw, for this purpose.

Another important feature of the invention is the possibility of achieving a high capacitance between contact ring and tube by allowing the ceramic plug and one of the

contact rings to extend all the way to one end of the tube. The ring and the tube will be separated by the ceramic, which is chosen to be insulating and thus is a dielectric. Connecting a small capacitor between the ring and the tube can increase the capacitance further.

Another important advantage of a high capacitance is that it helps avoid interference.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

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JC05 Rec'd PCT/PTO 21 FEB 2001

Device in connection with pacers

Technical field of the invention.

The present invention relates to pacer housings and more particularly to those parts of the housing intended for connection to the electrode leads.

Background of the invention.

Implantable pacers normally comprise a pacer housing (also called can) containing electronic circuitry and a unit for electric power as well as different electrodes which are connected to the interior parts in the pacer housing and which are to be implanted in or in the vicinity of the heart. The electrodes are connected to the pacer by means of leads. The internal parts of the pacers have to be well protected against the internal environment, especially the body fluids in the body for a long period of time, which places strict requirements on all entries into the interior of the can and especially on the connections of the leads to the housing. At the same time it should be possible to disconnect the pacer from the implanted leads for replacement or servicing of the pacer. The connective parts of the pacer and the leads have largely been standardized so as to encompass a relatively deep female socket comprising a number of contact surfaces whereas the leads are provided with a male part comprising one or several corresponding peripheral, generally circular contact surfaces.

At present the connective part of the pacer housing containing the female socket is made of a transparent material, normally of epoxy resin, which is molded onto the housing and onto contacts extending outwardly from the housing. The male part of the leads is normally locked by means of set screws, although other fastening means have been envisaged. The positioning and alignment of the different contact surfaces and of the fastening means or metallic threads for the set screws prior to the molding of

the connective part is however complicated and the delay in the manufacturing process incurred by the curing of the epoxy resin is considerable.

It would thus be desirable if the molding procedure could be dispensed with.

It has been discussed that these complexities could be avoided by designing the pacer with a socket located inside the metal housing. To our knowledge this kind of sockets, sometimes termed "black holes", are not used at present.

US-A-4,934,366 and US-A-5,324,311, both of which are incorporated by reference, describe two interior sockets or black holes for pacers. Both designs comprise a tubular member consisting of a number of longitudinally alternating sections made of metal respectively of insulating ceramics. An end section of metal can be welded or bonded to an opening in the pacer housing by means of a flange. The use of different materials however set high standards in regard of precision and durability of the component parts as well as on the assembly procedure thereof. This is especially important since the interior sockets must meet very high standards regarding the integrity of the interior of the pacer housing during long times of implantation in a demanding environment. The manufacture of these prior art sockets thus is relatively complicated.

Short description of the inventive concept

According to the invention the molding procedure can be avoided and the design of an interior socket can be simplified to a high degree whilst still meeting the required high standards by designing a pacer housing in accordance with the appended main claim. Preferred embodiments are set forth in the dependent claims.

Short description of the appended drawings

Fig 1 shows a conventional pacer housing with a transparent, molded connective part;

Fig 2 shows a lead with a male connective part;

Figs 3 - 6 show a preferred embodiment of the connective part in accordance with the present invention;

Detailed description of preferred embodiments of the invention.

Fig 1 illustrates a conventional pacer housing 1 having a molded, transparent connective part 2. The connective part 2 includes a female socket 3. The inner end of the socket 3 is provided with a longitudinal bore 7 having a relatively small diameter. The bore 7 is provided with a contact surface 4 adjacent to which threads 5 for a set or lock screw are located in a bore 6 oriented orthogonally relative to the female socket. The housing is hermetically sealed also in relation to the molded part 2 and the contact between the interior electronics and the contact surface 4 is achieved by means of a feed-through. The feed-through comprises a ceramic plug, typically made of alumina, into which one or more leads have been soldered. This lead is bonded (e.g. ultrasonically welded) to the electronics and to the contact surface 4. The ceramic plug is soldered or brazed by means of gold into a sleeve made of titanium. This operation may be made at any time before the assembly of the pacer housing. The sleeve is welded into an opening in the housing in a sealing manner during the assembly of the pacer housing that normally consists of two halves. Before the connective part is molded onto the housing, these halves are welded together and sealed.

Fig 2 illustrates a lead 15 comprising a proximal connecting plug 10 and a distal, transvenous, intracardial electrode 16 as well as an attachment means 17 for suturing the proximal end of the lead in the body of the patient. The connecting plug 10 is designed to be received in the socket 3 and the end thereof is provided with a longitudinally projecting contact pin 11 as well as a cylindrical body 17 provided with sealing rings 12, 13, 14 intended to engage and seal against the corresponding inner cylindrical surface of the female socket 3. The shape of the pin 11 corresponds to the shape of the bore 7. When the plug 10 is inserted into the socket 3 the pin 11 engages the contact surface 4 and the set-screw in the bore 6 can be tightened against the pin 11 in order to securely lock the plug 10 in the socket 3. The complexities involved in holding the bores, contact surfaces and threads in position and keeping them open and free from the molding material during the molding process are evident.

For the sake of simplicity, the above prior art device has been illustrated as being unipolar. A bipolar embodiment naturally will be more complex to manufacture. The preferred embodiments of the invention described below will relate to bipolar embodiments.

Figs 3 - 5 show a preferred embodiment of the invention comprising a tubular member 20. For the sake of clarity, the reference signs not repeated throughout all drawings.

The member comprises a tube 21 with two open ends 22, 23. Each end is to be welded into a respective opening in the pacer housing. The tube is made of the same metal as the pacer housing, in this case titanium. The mid-section of the tube is provided with two relatively small lateral openings 24, 25. The openings 24, 25 are sealed by means of a ceramic plug 26 fitting snugly in the tube and soldered with gold against the inside of the tube. Two contact rings 27, 28 have been molded into the ceramic plug overlapping the

lateral openings. The ceramic plug also originally could consist of several separate parts with the contact rings held between and soldered to these parts, thus uniting the parts of the plug to a unitary unit. The soldered junctions then would form an efficient seal.

It should be noted that the size of the openings 24, 25 being necessary to allow the bonding of the leads to the parts of the contact rings accessible through the openings 24, 25 and 31, 32 is small, seen in relation to the entire circumference and to the length of the tube. The openings thus do not affect the structural integrity of the tube. The contact rings 27, 28 moreover overlap the openings and are bonded thereto by means of the intermediate layer of ceramics, in this way strengthening the area in which said openings are located.

Typical dimensions for a tube intended to house a standard IS-1 male connector are for instance an inner diameter of 5 mm, a wall thickness of 0.3 mm (i. e. the same as the thickness of typical pacer housing walls) and a diameter of the holes 24, 25 of about 2 mm. A minimum area of about 4 mm^2 is necessary for the equipment presently used for bonding leads to metallic surfaces. The length of the tube is of course adapted to the specific housing into which it is to be placed, but might typically be about 25 mm.

These dimensions of course can be varied as long as the tube remains structurally intact, i. e. as long as the tube has a strength and rigidity that is sufficient to prevent loads, including thermal stresses, on the housing and/or the connector to be transferred as tensile forces to the ceramic parts. Of course, low tensile forces not exceeding the tensile strength of the ceramic could be accepted. Since there are standards regarding the loads a pacer housing and connector should be able to withstand and regarding the overall tightness of the housing, variations of the

dimensions only would involve standard stress calculations and dimensioning well within the scope of the man in the art. It should be noted that this also could take the degree of soldering between ceramic plug and tube into account, since this would determine the extent to which tube and ceramic would function as a composite without going outside the ordinary skill of the man skilled in the art.

The ceramic plug is provided with an interior bore corresponding to the shape of the male connector in the same way as the molded prior art female connector described above and thus includes interior sealing surfaces 52, 53 for engagement with the sealing rings on the male connector.

A part 30, 31 of the inside of the contact rings is not covered with the ceramic material. In this way two inner circumferential grooves are obtained in the inner bore of the ceramic plug. The bottom of the grooves consists of the metal in the contact rings. Two openings 32, 33 are also provided in the outer surface of the ceramic plug that may be made to coincide with the lateral openings 24, 25 in the tube wall. These openings give access to the contact rings 27, 28 when the ceramic plug has been mounted correctly in the tube 21.

Thus, when the ceramic plug 26 has been soldered or bonded into place, the openings 24, 25 will be completely sealed by the plug 26 although allowing electrical connection to the interior of the tube via the contact rings 27, 28.

To this extent the tubular member can be manufactured in advance as desired.

Both ends of the prefabricated tube can be welded to the pacer housing and the housing parts can be welded together after the connection of interior leads from the interior electronics to the contact rings, should this be desired.

The remaining parts, i. e. the means achieving the contact between the contact rings and the contact surfaces on the male connector part on the lead and the means locking or fixating the male connector part in the socket, can easily be inserted afterwards. This means for instance that these parts would not interfere with the standard helium-based procedures for testing the housing with connector for leaks or that these parts would not be affected by the leak testing procedure.

Fig 3 shows the main component parts of the tubular member, the tube 21 with openings 24, 25, the ceramic plug 26, a fixation part 40 and two circular spring contacts 57, 58. The spring contacts are similar to the spring contacts used in US-A-4,934,366.

The fixation part 40, shown in more detail in Fig 4, is designed in the same way as the lead locking device disclosed in US-A-4,784,141, herewith incorporated by reference, and comprises a hollow cylindrical part 41 fitting into the end of the tube 21. The inner end of the cylindrical part 41 is provided with an interior flange 42 with an inner conical surface 43. The locking device further comprises a resilient locking ring 44 located adjacent the flange 42. One side of the ring has a conical surface 45 that is complementary to the conical surface 43. The other side of the ring also has a conical surface 46 that is complementary to a conical surface 47 on a plug 48 provided with exterior threads 49 fitting into interior threads 50 on the inside of the cylindrical part 41. The outside of the plug 48 is provided with an O-ring 51 that is located in a peripheral groove 52 and sealingly engages the inside of the cylindrical part 41. When the plug 48 is screwed into the cylindrical part 41, the resilient ring 44 will be forced inwards into contact with the contact pin of the male connector part by means of the interaction of the different

conical surfaces, thus locking the contact pin inside the tube.

The tube 21 preferably is of the same material as the pacer housing, which normally is made of titanium. The ceramic plug may for instance be made of alumina, Al_2O_3, and the contact rings may for instance be made of stainless steel or of titanium.

In the above embodiment the ceramic plug has been illustrated as extending from the end of the tube and past the openings in the side of the tube. It is however only necessary that the ceramic plug cover the openings. The remaining part can be designed as a separate part inserted and bonded to the tube after the assembly of the pacer housing in a similar way as the fixation means.

Fig 4 shows the tube with all component parts mounted.

Fig 5 shows how the tube has been mounted in a pacer housing 60 and welded to openings 61, 62 in the openings via flanges located on the outside of the tube ends. Fig 5 also shows a male connector plug 110 inserted in the tubular member. The plug has a contact pin 111, a contact surface 118 and four sealing rings 112, 113, 114, 117. The resilient ring 44 grips the pin 111 and the sealing rings 112 - 114, 117 are in engagement with the interior sealing surfaces 52, 53.

The connector means can be achieved in a simple way compared with the prior art molded connector means.

As mentioned above, the ceramic part can be soldered into the tube in advance by similar methods as used when obtaining the feed-through in the prior art. The tube then is placed in the openings in one of the pacer housing halves and conductors 55, 56 are bonded (typically by means of ultrasonic welding) to the connecting parts of the

electronic board 54 and to the parts of the contact rings that are accessible via the openings in the tube. The housing halves then are assembled and the two halves and the ends of the tube are welded together by means of a laser beam to form a sealed unit. This unit then is tested for leakage, for instance by means of standard helium-based procedures. It should be noted that no other kinds of work operations than those already used in the prior art are necessary.

The pacer then is finished by slipping the resilient spring contacts into the respective interior grooves in the ceramic plug and by inserting and bonding the lead locking means into place in the corresponding open end of the tube.

The new connective part thus is very simple to manufacture and to mount in the pacer housing. The welding and sealing of the housing only includes the additional step of welding the ends of the tube to the edges of the openings in the housing, which is done in the same operation as the welding of the two housing halves. After the welding operation, no further operations are necessary, except for the simple insertion of contact rings and lead locking mechanism.

Since the tube after the welding operation in principle forms an integral, load-carrying part of the pacer housing, a high degree of tightness and integrity is obtained. The tube will ensure a high strength and a high durability of the connective part, whilst the ceramic plug will ensure a high degree of tightness in view of the large contact area between ceramic plug and tube that can used for soldering, i.e. sealing.

Although a pacer housing with one tubular member has been illustrated, the housing of course can contain several members. The housing also wholly or partly could be made of a non-metallic material as long as the parts in which the

openings holding the tube are of metal or of a material allowing a bond of sufficient strength to the metal tube. Furthermore, although the tube has been illustrated as having a circular cross-section, other cross-sections are possible.

One important advantage with the connector according to the invention is that the connecting pin 111 on the end of the lead can be reached from the outside through the end of the tube containing the lead locking means. This will facilitate the removal of the male connector from the female socket since the pin 11 can be pushed outwardly through said second end by means of a tool if the male connector proves to be difficult to pull out. In the above, preferred embodiment it is sufficient to unscrew the threaded plug 48, thus exposing the end of the contact pin 111. Furthermore, in this state a stylet could be introduced into the longitudinal channel, for instance for repositioning the electrode with the aid of the internal electronics in the pacer. The plug 48 could also contain a sealable, longitudinal bore, for instance sealed by a screw, for this purpose.

One important feature of the invention is the possibility of achieving a high capacitance between contact ring and tube by allowing the ceramic plug and one of the contact rings to extend all the way to one end of the tube. Ring and tube will be separated by the ceramic, which is chosen to be insulating and thus is a dielectricum. Connecting a small capacitor between ring and tube can increase the capacitance further.

One important advantage of a high capacitance is that it helps avoid interference.

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Claims

1. Pacer housing (60) comprising a connector means adapted to receive a contact plug (110) with contact surfaces (111, 118) on the proximal end of a lead (115) with an electrode located on the distal end of said lead, said housing preferably being made of metal, said connector means comprising a tubular member (20) having two ends (22, 23), said tubular member (20) being located inside said housing (60), a first end (23) of said tubular member (20) being welded or bonded to a first opening (62) in a wall of said housing (60), **characterized** in that said tubular member (20) comprises a tube (21) made of a metal being weldable or bondable to said housing (60), said tube (21) being structurally intact along its entire length, the second end (22) of said tube (21) being welded or bonded to a second opening (61) in said housing (60), all interior means (27, 28, 57, 58)in said tube contact the contact surfaces (111, 118) on said plug and are thus located within the enclosure formed by said tube (21) of metal, said metal tube (21) being provided with one or several lateral contact openings (24, 25) and with contact surfaces (27, 28) for establishing the contact to the interior of said housing, said contact surfaces (27, 28) being accessible through said openings (24, 25), said contact surfaces being electrically connected to contact means (57, 58) for contacting the contact surfaces (111, 118) on said plug (110).

2. Pacer housing according to claim 1, **characterized** in that said opening(s) (24, 25) are sealed by one or several insulating ceramic plugs (26) and said contacty surfaces (27, 28), said ceramic plugs being soldered or bonded to said tube, said plugs holding said contact surfaces (27, 28) for contacting the interior of said housing.

3. Pacer housing according to claim 2, **characterized** in that said contact surfaces comprise metal rings (27, 28) that are

AMENDED SHEET

molded or bonded into the ceramic plugs (26), the outside of said ceramic plugs (26) being provided with openings (32, 33) coinciding with said lateral contact openings (24, 25) in said tube, thus giving access to said metal rings from the outside of said tube.

4. Pacer housing according to claim 3, **characterized** in that a central part of said metal rings (27, 28) is free from ceramic and provides a circumferential groove (30, 31) at the inside of said rings (27, 28) giving access to said metal rings from the inside of said tube.

5. Pacer housing according to any one of the preceding claims, **characterized** in that lead locking means (40) are located in said second end (22) of said tube (21), and means (48) for operating said lead locking means (40) are accessible from said second end (22) of said tube (21).

6. Pacer housing according to claim 5, **characterized** in that said lead locking means (40) are removable wholly or partly to give access to said contact plug (110).

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Fig. 1

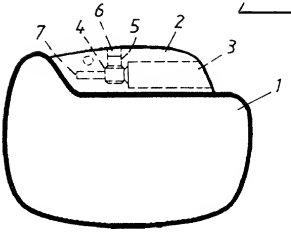


Fig. 2

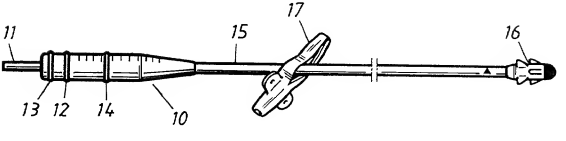


Fig.3

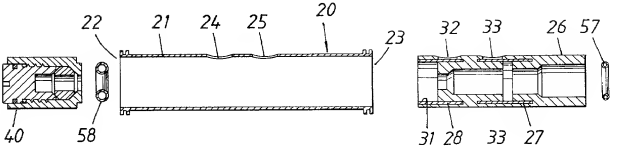


Fig.4

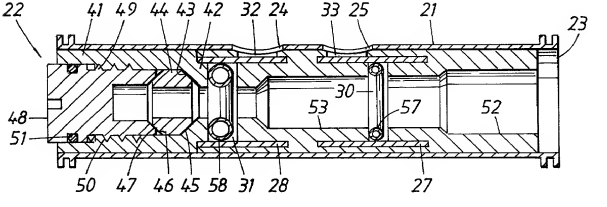
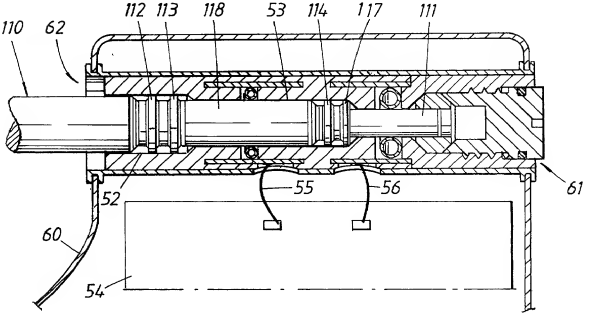


Fig.5



OIPE JC/62 APR 1 8 2001 PATENT & TRADEMARK OFFICE

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NUMBER **P01,0064**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"PACEMAKER HOUSING WITH LEAD CONNECTION ASSEMBLY" (AS AMENDED)

the specification of which (check only one item below):

□ is attached hereto.

■ was filed as United States application
Serial No. 09/763,387

on February 21, 2001,

and was amended

on February 21, 2001 (if applicable).

□ was filed as PCT international application

Number _____

on _____,

and was amended under PCT Article 19

on _____ (if applicable).

I hereby state that I have reviewed and understand the contest of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Sweden	9802928-3	31.08.98	■ YES □ NO
			□ YES □ NO
			□ YES □ NO
			□ YES □ NO
			□ YES □ NO

Combined Declaration For Patent Application and Power of Attorney (Continued)
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NO.
P01,0064

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, Untied States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

OIPE JC16
APR 18 2001
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U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.

PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

And I hereby appoint all Attorneys identified by the United States Patent & Trademark Office Customer Number 26574, who are all members of the firm of Schiff, Hardin & Waite.

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312/258-5790

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	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
Paul Brand	Rolf Hill	
DATE April 10, 2001	DATE April 10, 2001	DATE